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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/339,153	06/24/99	LUK	S 97-5201

HM12/0530

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EXAMINER	
KAUFMAN, C	

ART UNIT	PAPER NUMBER
1646	9

DATE MAILED: 05/30/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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Office Action Summary	Application No.	Applicant(s)	
	09/339,153	LOK ET AL.	
	Examiner	Art Unit	
	Claire M. Kaufman	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on _____ .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *7* .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

The amendment filed February 27, 2001 has been entered.

Response to Arguments

The rejection of claims under 35 USC 112, second paragraph, is withdrawn in view of the amendment filed 2/27/01. However, a new rejection is set forth below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Information Disclosure Statement

It is noted that Applicants say a diskette was provided with the IDS of 2/27/01 to aid in the analyzing of cited sequences. Unfortunately, the diskette is not in the application even though the IDS is. As the diskette was not a required submission, if Applicants would like to submit a duplicate diskette with the next response, they may. It would aid the Examiner. The diskette should be labeled clearly so that it is not mistaken for a "SEQUENCE LISTING" or "CRF" diskette by the USPTO staff.

No fee was paid with submission of the IDS of 2/27/01 and no explicit certification [§ 1.97(e)] was set forth in the IDS, but because it said the references were filed in accordance with 37 CFR 1.97, it will be assumed that the requirements of § 1.97(e) set forth have been met:

> That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the statement after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 1.56(c) more than three months prior to the filing of the information disclosure statement.

Sequences from the Incyte Pharmaceutical database is not considered "publicly" available by the USPTO, even though one may subscribe to the database. As a result, the references from that database have been considered, but will not be printed if this application

issues as a patent. The same is true for the "THC" sequences which appear to be from a private database.

Claim Rejections - 35 USC § 101 / 112, First Paragraph

Claims 1-19 remain and new claim 20 is rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth in the previous Office action (paper #5) on page 3.

Applicants argue that a DNA may have utility because, for example, "it hybridizes near a disease-associated gene or it has a gene-regulating activity", as set forth in the final Utility Guidelines (1/5/01, bottom of Comment 14). The argument has been fully considered, but is not persuasive. If the DNA hybridizes near, but itself is not associated with a disease, that is not sufficient for utility. The second to last sentence of comment 8 on page 1094 of the Guidelines is more clear, saying "An isolated and purified DNA molecule may meet the statutory utility requirements if, *e.g.*, it can be used to produce a useful protein or it hybridizes near and serves as a marker for a disease gene." That last part of the sentence is important. The gene of the instant invention maps in the 1p35.2 to 35.1 region (p. 23, lines 4-15) of the instant specification. Applicants have submitted evidence lining the genes in the 1p36 region to certain diseases (*e.g.*, neuroblastoma and melanoma). However, one cannot specifically map or analyze 1p36-associated diseases with a probe to 1p35.

Applicants argue that the tissue-specific expression of Zcytor 11 provides a real-world, specific and substantial utility, with the encoded protein capable of being used to produce antibodies cell localization, identification and isolation. The argument has been fully considered, but is not persuasive. Many proteins are expressed in the tissues in which Zcytor 11 has been found, so the use of antibodies against Zcytor 11 for tissue recognition is not specific. Because it is not know if cells expressing Zcytor 11 are unique in terms of disease association, the expression of the protein by a cell or identification or isolation of such a cell does not provide a substantial or specific utility.

Applicants argue that the claimed polypeptide can be used to tag chromosomes and, therefore, has a well established utility. The argument has been fully considered, but is not persuasive. This is not a specific utility since there are many polynucleotides in the prior art that

could be used to tag chromosome 1. Further, as discussed in the paragraph 2 above this, the specific band to which the Zcytor 11 polynucleotide is mapped is not itself associated with any known diseases.

Claim Rejections - 35 USC § 112

Claims 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 20 is indefinite because the metes and bounds of the claim are not clear. While the skilled artisan understands the general concept of hybridization under "stringent conditions", what specific conditions are intended by the use of the term "stringent" in the present claims is unknown. What conditions of stringency are used in any particular situation are determined by the specificity of hybridization desired by the practitioner. In this case, the desired specificity is unknown. The specification discusses general conditions considered "stringent", however, there is no defined set of conditions. Because the claimed polynucleotide must encode a particular polypeptide, the range or single set of intended hybridization conditions are necessary so it can be determined if the claim encompasses all possible coding polynucleotides or a more restricted set with a hybridization-defined structural relationship to SEQ ID NO:1.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Claire M. Kaufman, whose telephone number is (703) 305-5791. Dr. Kaufman can generally be reached Monday through Thursday from 8:30AM to 12:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached at (703) 308-6564.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. NOTE: If applicant *does* submit a paper by fax, the original signed copy should be retained by the applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office. **Please** advise the examiner at the telephone number above before facsimile transmission.

Claire M. Kaufman, Ph.D.

Patent Examiner, Art Unit 1646

May 30, 2001